REMARKS

Status of the Claims

Claims 1-49 are pending and stand various rejected under 35 U.S.C. §§ 101, 112, 102 and 103. Independent claim 1 has been amended as shown above to make explicit that the injection-molded polymer is absorbable, as described in original claim 2, which has been canceled without prejudice or disclaimer by amendment herein. Claim 27 has also been amended as shown above as requested by the Examiner. Claims 3, 13, and 39 have been amended to provide clear antecedent basis. Thus, claims 1 and 3-49 are pending as shown above.

35 U.S.C. § 101

Claims 27-49 was rejected as allegedly directed to non-statutory subject matter. (Office Action, page 2). Although Applicants disagree with this allegation, the foregoing amendments to claim 27 obviate this rejection.

35 U.S.C. § 112, Second Paragraph

Claims 13 and 39 were rejected under 112, second paragraph as allegedly indefinite. (Office Action, page 3). In particular, there was alleged to be no antecedent basis for the recitation "the linking elements." Applicant has corrected the unintended error by amendment herein, thereby obviating this rejection.

35 U.S.C. § 102(b) over Ritchart

Claims 1-7, 11, 13, 14, 16, 24, 26-33, 37, 39, 40, 42, 45, 47 and 48 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 4,994,069 (hereinafter "Ritchart"). In support of this rejection, the Examiner states, in part:

> Ritchart et al. teach a vaso-occlusive device and method for forming the device (re claims 1, 26, 28 and 48). Ritchart et al. teach and occlusive element 48 (figure 6, for example), comprising an injection-molded material formed into a three-dimensional configuration. Ritchart et al. teach the device comprising a wire 46 being formed from a flexible preshaped polymer tube (see column 6, lines 16-30). The singly molded tube (re claims 11 and 37) is taught as including an inside or an outside coating of collagen (column 5, last line) for contacting with aneurysm the structure ... (Office Action, page 3).

Because Ritchart does not describe, demonstrate or suggest the methods of pending claims 1 and 3-26 or the devices of pending claims 27-49, Applicants traverse the rejection.

With regard to the pending method claims, there is no disclosure in Ritchart of methods of injection-molding polymeric devices that are absorbable. Ritchart discloses only biodegradable polymers (col. 6, lines 16-30), none of which are absorbable as claimed. Accordingly, Ritchart does not teach or suggest the methods as claimed.

Turning to claims 27-49, Applicants note the following. The devices as set forth in these claims do not assume a different three-dimensional configuration upon deployment. By contrast, Ritchart is clear that all of his devices are advanced through a catheter in the stretched, linear condition and assume a randomly coiled configuration upon deployment. *See, e.g.,* Abstract of Ritchart. Thus, unlike the claimed devices, Ritchart's devices are not formed into a three-dimensional configuration and deployed in that same three-dimensional configuration, as claimed. As such, Ritchart does not anticipate pending claims 27-49 and withdrawal of this rejection is respectfully requested.

35 U.S.C. § 102(b) over Palermo

Claims 1, 4-7, 9, 12-17, 22-27, 30-33, 35, 38-43, 45, 46 and 48 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,925,059 (hereinafter "Palermo") for the reasons set forth on page 4 of the Office Action.

The foregoing amendment to independent claim 1, which incorporated the limitations of unrejected claim 2 therein, obviates the rejections of claims 1, 4-7, 9, 12-17 and 22-26 over Palermo.

With respect to claims 27, 30-33, 35, 38-43, 45, 46 and 48, Applicants submit that Palermo fails to describe or suggest a device that does not change its configuration upon deployment. Indeed, Palermo clearly describes, for example, at col. 8, lines 35-38 how "the coil assembly show assumes a second diameter when ejected from the tip of the catheter... ." Because Palermo does not describe or demonstrate devices that are formed and deployed in the same configuration, this reference cannot anticipate the pending claims and withdrawal of this rejection is respectfully requested.

35 U.S.C. § 102(b) over Berenstein

Claims 27, 28, 30-32, 40, 41, and 45-47 stand rejected as allegedly anticipated by U.S. Patent No. 5,690,666 (hereinafter "Berenstein for the reasons set forth on pages 5-6 of the Office Action.

Pending claims 27, 28, 30-32, 40, 41, and 45-47 are directed to devices that are formed in a particular three-dimensional configuration and, moreover, which are deployed into a body cavity in that same three-dimensional configuration. In contrast, Berenstein is directed entirely to devices that are deployed in a first, linear configuration and, after deployment, assume "a

loose, random mass of threadlike material after being ejected from the catheter tip at the chosen vascular site." *See,* Abstract of Berenstein. Thus, because Berenstein does not teach or suggest devices that are deployed in their final three-dimensional configuration, this reference cannot anticipate any of the pending claims.

35 U.S.C. § 102(e) over Porter

Claims 1-6, 9, 14-17, 19-21, 24-32, 40-43, 45 and 47-49 stand rejected as allegedly anticipated by U.S. Patent No. 6,547,804 (hereinafter "Porter") for the reasons set forth on page 7 of the Office Action.

Claim 1 and claims dependent therefrom are directed to methods of making a vaso-occlusive device by injection molding an absorbable polymer. Porter fails to disclose such methods. Rather, with respect to injection-molded devices, the only material Porter discloses as suitable for injection-molding is polyisoprene, which is clearly not absorbable. *See,* col. 3, lines 32-35. All other teachings in Porter regarding polymers and the like are completely unrelated to injection molding. Thus, Porter does not anticipate pending claims 1-6, 9, 14-17, 19-21 and 24-26.

Similarly, pending claims 27-49 are all directed to devices that are in their final configuration before deployment. In contrast, Porter is directed entirely to "high distensible" balloons. *See, e.g.,* Title and Abstract of Porter. Plainly, disclosure of devices that are distensible after deployment cannot anticipate the pending claims 27-49, all of which are drawn to devices that are deployed in the same configuration as they are formed.

Thus, Applicants submit that Porter does not anticipate any of the pending claims and respectfully request that this rejection be withdrawn.

35 U.S.C. § 102(e) over Mitelberg

Claims 27, 30-34, 38, 45, 46 and 49 were rejected as allegedly anticipated by U.S. Patent No. 6, 613,074 (hereinafter "Mitelberg") for the reasons set forth on page 8 of the Office Action.

Like Ritchart, Palermo, Porter, and Berenstein, Mitelberg does not teach or suggest vaso-occlusive devices that are formed into a three-dimensional configuration and deployed into a body cavity in that same configuration. Instead, Mitelberg relates to a "collapsible" device that expands upon deployment. *See, e.g.,* Abstract and col. 2, lines 35-40 of Mitelberg.

Therefore, Mitelberg fails to teach or suggest all the elements of pending claims 27, 30-34, 38, 45, 46 and 49 and, accordingly, cannot anticipate these claims.

35 U.S.C. § 103(a) over Marotta

Claims 1-8, 10, 11, 14, 15, 19, 21, 22, 24, 26-34, 36, 37, 40, 41 and 45-49 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 6,261,305 (hereinafter "Marotta" or "the primary reference") in view of U.S. Patent No. 6,200,335 (hereinafter "Igaki"). Claims 18 and 44 were rejected as allegedly obvious over Marotta in view of Igaki and in further view of U.S. Patent No. 6,293,960 (hereinafter "Ken"). (Office Action, pages 8-11). In particular, it is alleged that Marotta teaches the invention "substantially as claimed." (Office Action, page 8. Although it is acknowledged that Marotta does not teach injection molding to prepare the devices, Igaki is cited for teaching micro-machining of a tube "being formed of a polymer which has biological compatibility and including the absorptive qualities of polylactic acid." (Office Action, page 10). In reference to claims 18 and 44, Marotta and Ken are cited as above and Ken is cited for allegedly teaching a balloon and the connection between the pusher and the balloon. (Office Action, page 11).

Applicants traverse the rejections.

Marotta does not, as asserted by the Office, teach the invention substantially as claimed. Regarding method claims 1-8, 10, 11, 14, 15, 19, 21, 22, 24 and 26, Marotta provides absolutely no teaching or suggestion to make a device by injection-molding of an absorbable polymer. Ken is also silent regarding injection molding of absorbable polymers.

Furthermore, there is no motivation in Marotta or Igaki to combine their disclosures to arrive at the claimed methods. Marotta is silent as to injection molding of absorbable polymers. Igaki is completely silent to as to methods of making vaso-occlusive devices. Indeed, because the stents disclosed in Igaki are designed to hold vessels open while vaso-occlusive devices are designed to occlude vessels, one of skill in the art would have had no motivation to use injection molding as described in Igaki to make vaso-occlusive devices as claimed. Because there is no motivation to combine Marotta and Igaki, claims 1-8, 10, 11, 14, 15, 19, 21, 22, 24, and 26 cannot be obvious over Marotta in view of Igaki and in further view of Ken.

Similarly, Marotta fails entirely to teach or suggest the vaso-occlusive devices of pending claims 27-49. To reiterate, pending claims 27-49 are all drawn to vaso-occlusive devices that do not change shape upon deployment into a body cavity. Marotta's devices all contain an "expandable leaf portion" that is "independently moveable" and, upon deployment, can be "urged against" the opening of an aneurysm. *See, e.g.,* Title and Abstract of Marotta. Ken also relates to expanding devices, particularly balloons. Unlike the devices as claimed, Marotta's and Ken's devices are designed to (and indeed must) change shape upon deployment. Therefore, there is no combination of Marotta and Ken that would result in the devices as claimed.

Nor is there any motivation to combine Igaki with Marotta (or Ken) or any combination that would reasonably lead one of skill in the art to claimed devices. Igaki relates to a different field of endeavor, namely keeping vessels open instead of occluding them, as claimed. The

skilled artisan would have had no reason to use devices that change configuration upon deployment based on diverse disclosures of stents and vaso-occlusive devices in view of their completely different functions and purposes.

In sum, there is no suggestion in any of the cited references to arrive at the claimed methods and devices. Marotta and Ken are silent as to injection molding or absorbable polymers and devices that are formed and deployed in the same shape. Moreover, nowhere do these references suggest that injection-molding techniques or preformed devices that do not change shape upon deployment. For its part, Igaki is completely silent as to vaso-occlusive devices or methods of making such devices, as claimed. Obviousness cannot be established by asserting that the individual elements were known and that the motivation to combine somehow derives from unrelated disclosures of these elements. Simply put, there is absolutely no suggestion or reason given in Marotta, Igaki or Ken to combine their teachings to arrive at the claimed methods or devices. Therefore, the obviousness rejections are based on improper hindsight reconstruction and should be withdrawn.

CONCLUSION

For the reasons discussed above, Applicant submits that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: February 26, 2004

By: Dasternak

Dahna S. Pasternak
Attorney for Applicant
Registration No. 41,411

ROBINS & PASTERNAK LLP
1731 Embarcadero Road
Suite 230
Palo Alto, CA 94303
Tel. (650) 493-3400
Fax. (650) 493-3440